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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

HELMS, LARRY RONALD

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/780,669

Applicant(s)

XU ET AL.

Examiner

Larry R. Helms

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 21 is/are allowed.
- 6) ☒ Claim(s) 18-20 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/22/04, 10/19/01, 5/18/02
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 18, 21 have been amended.
2. Claims 18-22 are pending and under examination.
3. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.
4. The following Office Action contains ~~some~~ NEW GROUNDS of rejection.

Priority

5. The instant application is a CIP of several applications. Claim 18 recites a compositions comprising a first component either carriers or immunostimulants and a second component of an antibody or antigen binding fragment that binds SEQ ID NO:114. The first apparent mention of the limitation of "immunostimulants" is seen in the 09/439,313 application. Therefore the claims are granted the priority of the 09/439,313 application which is 11/12/99.

Rejections Withdrawn

6. The rejection of claims 18-20 and 22 under 35 U.S.C. 102(e) as being anticipated by Hillman et al (US Patent 6,020,478, filed 2/28/97) is withdrawn in view of the new grounds of rejections below.

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7. The rejection of claims 18-20 and 22 under 35 U.S.C. 103(a) as being unpatentable over Hillman et al (US Patent 6,020,478, filed 2/28/97) and further in view of Gillies (US Patent 5,650,150, issued 7/97) is withdrawn in view of the new grounds of rejections below.

8. The rejection of claims 18-20 and 22 under 35 U.S.C. 103(a) as being unpatentable over Hillman et al (US Patent 6,020,478, filed 2/28/97) and further in view of Fujiwara et al (Cancer Chemother Pharmacol 38:s22-26, 1996) is withdrawn in view of the new grounds of rejections below.

The following are NEW GROUNDS of Rejections

9. Claims 18-20 and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Hillman et al (US Patent 6,020,478, filed 2/28/97) as evidenced from Cruse et al (Illustrated Dictionary of Immunology, CRC Press, New York, page 241, 1995).

The claims recite a composition comprising a carrier and an antibody to residues 120-139, 151-169, or 165-184 of SEQ ID NO:114 wherein the antibody is a polyclonal and the composition is effective for inhibiting tumor growth. For this rejection the intended use for inhibiting tumor growth is given no patentable weight for claim 22.

Hillman et al teach SEQ ID NO:1 which is identical to the instant SEQ ID NO:114. Hillman et al teach polyclonal antibodies to the protein and carriers and the antibodies

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can be used for treatment of cancer (see column 7, column 16, lines 20-65, column 19, lines 45-60, column 21, lines 30-50). As evidenced from Cruse et al polyclonal antibodies bind to different epitopes on an antigen and represent the natural consequence of an immune response. Thus, Cruse teach that polyclonal antibodies are directed to many epitopes on an antigen.

Although Hillman et al does not specifically teach the polyclonal antibody specifically binds residues 120-139, 151-169, or 165-184 of SEQ ID NO:114, because of the nature of polyclonal antibodies as evidenced from Cruse, one would expect the polyclonal sera to contain antibodies to the recited epitopes in the protein. Since the Patent and Trademark Office does not have the facilities for examining and comparing the claimed polyclonal antibody with the antibody of Hillman et al, the burden of proof is upon the Applicants to show a distinction between the structural and functional characteristics of the claimed antibody and antibody of the prior art. See In re Best, 562 F.2d 1252, 195 U.S.P.Q. 430 (CCPA 197) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

The response filed 12/22/04 has been carefully considered but is deemed not to be persuasive. The response states that Hillman et al does not teach antibodies that binds to amino acid residues 120-139, 151-169, 165-184 of SEQ ID NO:114 (see page 5 of response). In response to this argument, as indicated above one would reasonably conclude that the polyclonal antibodies of Hillman et al would have antibodies that bound the claimed residues.

10. Claims 18-20 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hillman et al (US Patent 6,020,478, filed 2/28/97) as evidenced from Cruse et al (Illustrated Dictionary of Immunology, CRC Press, New York, page 241, 1995) and further in view of Gillies (US Patent 5,650,150, issued 7/97).

Claims 19-20 and 22 have been described supra as well as the interpretation of claim 22, claim 18 recites a composition comprising an antibody to residues 120-139, 151-169, or 165-184 of SEQ ID NO:114 and an immunostimulant.

Hillman et al teach SEQ ID NO:1 which is identical to the instant SEQ ID NO:114. Hillman et al teach polyclonal antibodies to the protein and carriers and the antibodies can be used for treatment of cancer (see column 7, column 16, lines 20-65, column 19, lines 45-60, column 21, lines 30-50). As evidenced from Cruse et al polyclonal antibodies bind to different epitopes on an antigen and represent the natural consequence of an immune response. Thus, Cruse teach that polyclonal antibodies are directed to many epitopes on an antigen.

Although Hillman et al does not specifically teach the polyclonal antibody specifically binds residues 120-139, 151-169, or 165-184 of SEQ ID NO:114, because of the nature of polyclonal antibodies as evidenced from Cruse, one would expect the polyclonal sera to contain antibodies to the recited epitopes in the protein. Since the Patent and Trademark Office does not have the facilities for examining and comparing the claimed polyclonal antibody with the antibody of Hillman et al, the burden of proof is

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upon the Applicants to show a distinction between the structural and functional characteristics of the claimed antibody and antibody of the prior art. See In re Best, 562 F.2d 1252, 195 U.S.P.Q. 430 (CCPA 197) and *Ex parte Gray*, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

Hillman et al does not teach an immunostimulant with the antibody. This deficiency is made up for in the teachings of Gillies.

Gillies teach fusion protein comprising anti-tumor antibodies and cytokines for the treatment of tumors.

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to have produced a composition comprising a polyclonal antibody to the specific residues of SEQ ID NO:114 and a cytokine for inhibiting tumor growth.

One of ordinary skill in the art would have been motivated to and had a reasonable expectation to have produced a composition comprising a polyclonal antibody to the specific residues of SEQ ID NO:114 and a cytokine for inhibiting tumor growth because Hillman et al teach polyclonal antibodies for treatment of tumors and Gillies teach antibody cytokine fusion proteins for treatment of tumors wherein the antibody binds to a tumor antigen and the cytokine results in stimulation of a T cell response (see column 3 of Gillies). The antibodies of Gillies are from Ig-producing lymphoid cells and as such it would be obvious that they can be polyclonal (see column 6 and 7). Since claim 1 does not recite that the components are separate components

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a fusion protein of an antibody and a cytokine would read on the claims. Thus the are reads on the claims.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

The response filed 12/22/04 has been carefully considered but is deemed not to be persuasive. The response states that Hillman et al does not teach antibodies that binds to amino acid residues 120-139, 151-169, 165-184 of SEQ ID NO:114 (see page 5-6 of response). In response to this argument, as indicated above the one would reasonably conclude that the polyclonal antibodies of Hillman et al would have antibodies that bound the claimed residues.

11. Claims 18-20 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hillman et al (US Patent 6,020,478, filed 2/28/97) as evidenced from Cruse et al (Illustrated Dictionary of Immunology, CRC Press, New York, page 241, 1995) and further in view of Fujiwara et al (Cancer Chemother Pharmacol 38:s22-26, 1996).

Claims 19-20 and 22 have been described supra as well as the interpretation of claim 22, claim 18 recites a composition comprising an antibody to SEQ ID NO:114 and an immunostimulant.

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Hillman et al teach SEQ ID NO:1 which is identical to the instant SEQ ID NO:114. Hillman et al teach polyclonal antibodies to the protein and carriers and the antibodies can be used for treatment of cancer (see column 7, column 16, lines 20-65, column 19, lines 45-60, column 21, lines 30-50). As evidenced from Cruse et al polyclonal antibodies bind to different epitopes on an antigen and represent the natural consequence of an immune response. Thus, Cruse teach that polyclonal antibodies are directed to many epitopes on an antigen.

Although Hillman et al does not specifically teach the polyclonal antibody specifically binds residues 120-139, 151-169, or 165-184 of SEQ ID NO:114, because of the nature of polyclonal antibodies as evidenced from Cruse, one would expect the polyclonal sera to contain antibodies to the recited epitopes in the protein. Since the Patent and Trademark Office does not have the facilities for examining and comparing the claimed polyclonal antibody with the antibody of Hillman et al, the burden of proof is upon the Applicants to show a distinction between the structural and functional characteristics of the claimed antibody and antibody of the prior art. See In re Best, 562 F.2d 1252, 195 U.S.P.Q. 430 (CCPA 197) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

Hillman et al also teach antibodies can be used to treat cancer and the antibodies can be combined with other therapy such that one may achieve therapeutic efficacy with lower dosages of each agent, thus reducing the potential side adverse effects (see column 16, lines 36-52). Hillman et al does not teach an immunostimulant with the antibody. This deficiency is made up for in the teachings of Fujiwara et al.

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Fujiwara et al teach treatment of tumors with IL-12 and the addition of IL-12 leads to tumor regression (see entire document).

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to have produced a composition comprising a polyclonal antibody to the specific residues of SEQ ID NO:114 and a cytokine for inhibiting tumor growth.

One of ordinary skill in the art would have been motivated to and had a reasonable expectation to have produced a composition comprising a polyclonal antibody to the specific residues of SEQ ID NO:114 and a cytokine for inhibiting tumor growth because Hillman et al teach antibodies for treatment of tumors with other agents so that lower dosages can be used. In addition, one of ordinary skill in the art would have been motivated to and had a reasonable expectation to have produced a composition comprising a polyclonal antibody to the specific residues SEQ ID NO:114 and a cytokine for inhibiting tumor growth because Fujiwara et al teach that the cytokine IL-12 leads to tumor regression.

The motivation to combine can arise from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combine for their common known purpose. Section MPEP 2144.07. Versus See MPEP 2144.06.

It is prima facie obvious to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; idea of combining them flows logically from their having

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been individually taught in prior art. In re Kerkhoven, 205 USPQ 1069, CCPA 1980.

See MPEP 2144.06.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

The response filed 12/22/04 has been carefully considered but is deemed not to be persuasive. The response states that Hillman et al does not teach antibodies that binds to amino acid residues 120-139, 151-169, 165-184 of SEQ ID NO:114 (see page 6 of response). In response to this argument, as indicated above the one would reasonably conclude that the polyclonal antibodies of Hillman et al would have antibodies that bound the claimed residues.

Conclusion

12. Claim 21 is in condition for allowance.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (571) 272-0832. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787.

15. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center telephone number is 571-273-8300.

Respectfully,

Larry R. Helms Ph.D.

571-272-0832



LARRY R. HELMS, PH.D
PRIMARY EXAMINER